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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,768	12/05/2003	Peter M. Bonutti	2500DV2CN2DV3CN5	3380

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EXAMINER
THALER, MICHAEL H

ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/729,768

Applicant(s)

BONUTTI, PETER M.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Jan. 8, 2007 has been entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-20 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear what "Such shapes may include, for example, wedge or U-shaped filaments that collapse at the skin, then expand at deep tissue planes for visualization and working space." (page 15, lines 7-9) means. For example, does this mean that the shape

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may include a plurality of inflatable filaments instead of a single balloon similar to the inflatable filaments described on page 22, lines 18-21? Or does it mean that the shape may include a plurality of non-inflatable filaments instead of a single balloon similar to the non-inflatable filaments described on page 22, lines 13-18? Or does it mean that the structure may still be a single balloon with a plurality of filaments embedded within the wall of the balloon. Or does it mean that the structure may still be a single balloon with a plurality of filaments within the cavity of the balloon but not attached thereto? Or does it mean that the structure may still be a single balloon with a plurality of filaments attached to the outside of the balloon? Or does it mean that the structure may still be a single balloon with a plurality of filaments embedded within the wall of the balloon, such that the balloon has smooth inner and outer surfaces? Or does it mean that the structure may still be a single balloon with a plurality of filaments embedded within the wall of the balloon, such that the balloon has ridges or ribs in inner and outer surfaces corresponding to the location of the filaments? Further, what makes the filaments expand? Further, how can a filament be wedge-shaped since a wedge is usually a three dimensional object (with

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significant width to perform the wedging action) while a filament is a thin strand with very little width?

Claims 15-20 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the original disclosure for the limitations in claim 15, lines 6-7 that the filaments are within an interior of the bladder and define at least in part its shape.

Claims 15-20 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claims is unclear for the reasons set forth above.

Claims 15-20 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon (3,417,745) in view of Grayzel (4,796,629). Sheldon, in figure 3, discloses shaft 56 and inflatable bladder 57 which has an eccentric shape upon inflation and cannula 5. Alternatively, the inflatable bladder 57 in figure 4 has the shape of a wedge since it tapers in the

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proximal direction. The Sheldon bladder, when inflated and axially moved with respect to the cannula, is inherently capable of separating adjacent layers of tissue since the bladder is made of the very strong inelastic material of Mylar (col. 8, lines 55-58) and is filled with a substantially non-compressible material which is liquid (the fluid in the phrase "fluid or gas" referred to in col. 8, line 68) which is substantially non-compressible. Cannula 5 has an opening at a proximal end portion, an opening at a distal end portion and defining a passage "therethrough" when it is expanded as described in col. 3, lines 19-36. Sheldon fails to disclose a plurality of filaments within an interior of the inflatable bladder. However, Grayzel teaches that a plurality of filaments 860 should be disposed within an interior of an inflatable bladder 842 (which is used inside the body to separate tissues) in order to obtain the advantage of reinforcing it and thus preventing its ripping or rupture (col. 5, lines 43-54). It would have been obvious to include a plurality of filaments in the Sheldon bladder so that it too would have this advantage. As to claim 16, Mylar (col. 8, lines 55-58) does not stretch when fully inflated. As to claim 19, shaft 56 is rigidified when attached to rigid shaft 2 (col. 2, lines 39-40 and 60-63). As to claims

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27 and 28, each Grayzel filament 860 is U-shaped and wedge shaped in its the lower half.

Claims 15-20 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froning (3,875,595) in view of Grayzel (4,796,629). Froning discloses shaft 47, 48, inflatable bladder 46 which has an eccentric shape upon inflation (since the portion on one side of the longitudinal axis of shaft 47, 48 is larger than the portion on the other side of the longitudinal axis) and cannula 31. The Froning bladder, when inflated and axially moved with respect to the cannula, is inherently capable of separating adjacent layers of tissue since the bladder is made of material which is sufficiently strong to hold fluid under pressure (col. 3, lines 17-21) and is filled with a substantially non-compressible material (the water described in col. 3, lines 17-21). Froning fails to disclose a plurality of filaments within an interior of the inflatable bladder. However, Grayzel teaches that a plurality of filaments 860 should be disposed within an interior of an inflatable bladder 842 (which is used inside the body to separate tissues) in order to obtain the advantage of reinforcing it and thus preventing its ripping or rupture (col. 5, lines 43-54). It would have been obvious to include a plurality of filaments in the Froning bladder so that it too would have this advantage. As to claim

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16, stretching of bladder 46 will be finished when it is fully inflated. As to claim 19, portion 48 of the shaft is rigid.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571) 272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

mht



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731